

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

To:

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Date of mailing
(day/month/year) 21 FEBRUARY 2005 (21.02.2005)

Applicant's or agent's file reference
DBT/031001/Y

IMPORTANT NOTIFICATION

International application No.

PCT/KR2003/002175

International filing date (day/month/year)

17 OCTOBER 2003 (17.10.2003)

Priority date (day/months/year)

17 OCTOBER 2002 (17.10.2002)

Applicant

DIGITAL BIOTECH CO., LTD. et al

1. The applicant is hereby notified that International Preliminary Examining Authority transmits here with the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**
The applicant must enter the national phase before each elected office by performing certain acts (filing translations and paying national fees) within 30 month(s) from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details in the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/KR



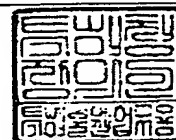
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TENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DBT/031001/Y	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2003/002175	International filing date (day/month/year) 17 OCTOBER 2003 (17.10.2003)	Priority date (day/month/year) 17 OCTOBER 2002 (17.10.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 C07C 335/04, C07C 275/64, C07C 327/38		
Applicant DIGITAL BIOTECH CO., LTD. et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>3</u> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of _____ sheets.
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand <div style="text-align: center; font-weight: bold;">16 APRIL 2004 (16.04.2004)</div>	Date of completion of this report <div style="text-align: center;">07 FEBRUARY 2005 (07.02.2005)</div>
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer <div style="text-align: center;">KIM, YONG</div> Telephone No. 82-42-481-8148 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/002175

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement) under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed; unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is.

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed," and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2003/002175

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-18	YES
	Claims	None	NO
Inventive step (IS)	Claims	9, 10	YES
	Claims	1-8, 11-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims	None	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: WO 02/16318 A1 (28 Feb. 2002)

D2: WO 02/16319 A1 (28 Feb. 2002)

The present invention relates to N-hydroxythiourea, N-hydroxyurea and N-hydroxyamide compounds as a vanilloid receptor antagonist and the pharmaceutical compositions comprising the same.

D1 and D2 which are considered to represent the most relevant state of the art, disclose thiourea, urea and amide compounds as a vanilloid receptor antagonist and the pharmaceutical compositions comprising the same.

1. Novelty

N-Hydroxythiourea, N-hydroxyurea and N-hydroxyamide compounds of claims 1 to 10 are novel in that they have thiourea, urea and amide moiety *substituted with the hydroxy group*, whereas the compounds of D1 and D2 have *unsubstituted* thiourea, urea and amide moiety. Since the compositions of claims 11 to 17 are characterized by the novel compounds of claims 1 to 10, the compositions of these claims are also novel. Moreover, a use claim 18 for the compositions is also novel.

Consequently, the subject matter of the present claims 1 to 18 is considered to be novel under PCT Article 33(2).

2. Inventive Step

N-Hydroxythiourea and N-hydroxyurea compounds of the present invention (claims 1 to 8) are structurally very close to the compounds of D1 and D2 in that they have *N-hydroxythiourea and N-hydroxyurea* moiety, and the compounds of D1 and D2 have *thiourea and urea moiety*. Furthermore, it is not considered that the compounds of claims 1 to 8 show more potent analgesic activity than the compounds of D1 and D2 (see Table 9 in the present invention).

Since the compositions and their use of claims 11 to 18 are characterized by the non-inventive compounds of claims 1 to 8, the compositions and their use of these claims also lack inventive step.

Consequently, the subject matter of the present claims 1 to 8 and 11 to 18 lack an inventive step under PCT Article 33(3).

3. Industrial Applicability

There is no reason for denying industrial applicability of this invention. Consequently, claims 1 to 18 appear to meet the requirement of PCT Article 33(4).